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Signature

January 17, 2007

Date of Signature

Re: Application of:

Serial No.:

Keeven et al.

10/748,449

Filed:

December 30, 2003

For:

Augments for Surgical Instruments

**Group Art Unit:** 

3733

Confirmation No.

2371

Examiner:

Annette R.Reimers

J&J Reference:

DEP5038USNP

MMB Docket No.

1671-0281

#### TRANSMITTAL OF REPLY BRIEF

Please find for filing in connection with the above patent application the following documents:

- 1. Reply Brief (14 pages); and
- 2. One (1) return post card.
- 3. Two (2) Attachments.

Commissioner for Patents January 17, 2007 Page 2 of 2

Applicants believe no fee is required for filing of this Reply. However, please charge any fee deficiency or credit any overpayment to Deposit Account No. 13-0014.

Respectfully Submitted,

MAGINOT, MOORE & BECK

/James D. Wood/

January 17, 2007

James D. Wood Registration No. 43,285 Chase Tower 111 Monument Circle, Suite 3250 Indianapolis, IN 46204-5109

**Enclosures** 

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

J&J Reference No. DEP5038USNP

MMB Docket No. 1671-0281

Application of: Keeven et al.

Serial No. 10/748,449

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Examiner: Annette R. Reimers

Group Art Unit: 3733

**AUGMENTS FOR SURGICAL INSTRUMENTS** 

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/James D. Wood/

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January 17, 2007

Date of Signature

#### **REPLY BRIEF**

Sir:

This is a reply submitted in response to the Examiner's Answer mailed on November 17, 2007.

#### **Discussion**

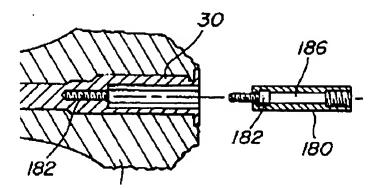
The Examiner has attributed to the cited references teachings which are clearly absent from the references, made new allegations and attributed arguments to the Appellants which the Appellants have not made. While the discussion set forth in the Applicant's Appeal brief clearly and correctly discuss the relevance of the prior art cited by the Examiner, certain topics raised in the Examiner's Answer are discussed below to clarify the actual teaching of the cited references and the basis for the present appeal.

#### 1. The Examiner Has Misconstrued the Claims

The Examiner's Answer, for the first time, alleges a particular component of Ritter as the component which allegedly anticipates the intramedullary pin recited in the Appellants' claims. Specifically, the Examiner now alleges that FIG. 20 of Ritter "discloses an intramedullary pin, i.e. 182, which is received in the guide slot, i.e., 32, of the positioning member, i.e., 30." (Examiner's Answer at page 6). The Examiner's construction of an "intramedullary pin" is unreasonable.

Specifically, the screw 182 of Ritter is merely an alternative embodiment of the mechanism for varying the position of the femoral provisional 96 with respect to the intramedullary rod 30. (Ritter at column 11, lines 2-12). Thus, the screw 182 is inserted within the "threaded portion 184 of the blind bore 36 so as to secure the angled support member 180 to the blind bore 36." (Ritter at column 11, lines 6-8 and FIG. 20, a portion

of which appears below, wherein the threaded portion 184 is mistakenly identified by the reference number "182" at the left of the figure).



Thus, without previously providing any hint of such a construction, the Examiner has construed an "intramedullary pin" to encompass the screw 182. The screw 182 does not contact any portion of the bone. Thus, under the Examiner's construction, an "intramedullary pin" need not be in contact with any portion of the bone. Rather, the component merely needs to be located within an envelope defined by the outer portion of the bone.

The Federal Circuit has stated that "[a]lthough the PTO must give claims their broadest reasonable interpretation, this interpretation must be consistent with the one that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1356, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999), citing *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Bond*, 910 F.2d 831, 833, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). Additionally, "the person of ordinary skill in the art is deemed to read the claim

The Examiner alleges that the Appellants had argued that "the system of Ritter et al. does not have an intramedullary pin." (Examiner's Answer at page 6). The Examiner has failed to identify where the Appellants make any such assertion. After a review of the Appellants' brief, the Appellants are not able to identify any such assertion. Rather, the Appellants merely pointed out the incomplete nature of the Examiner's rejection in that the Examiner failed to even allege that Ritter disclosed an intramedullary pin as recited in claims. (Appeal Brief at page 17).

term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips v. AWH*Corp., 415 F.3d 1303, 1313, 75 USPQ2D 1321, 1326 (Fed. Cir. 2005).

As defined in the *Merriam-Webster's Medical Dictionary*, © 2002 Merriam-Webster, Inc, the adjective "intramedullary" is defined as "situated or occurring within a medulla <an intramedullary tumor of the spinal cord>; especially: involving use of the marrow space of a bone for support <intramedullary pinning of a fracture of the thigh>.

Thus, while the preferred construction of the word "intramedullary" requires the bone to support the object of the adjective, the broadest possible construction could arguably merely require the object to be located within an envelope defined by the outer portion of the bone. The word "pin" in the medical field is defined as "1: a metal rod driven into or through a fractured bone to immobilize it; 2: a metal rod driven into the root of a reconstructed tooth to provide support for a crown or into the jaw to provide support for an artificial tooth." *Merriam-Webster's Medical Dictionary*, © 2002 Merriam-Webster, Inc. Thus, the term "intramedullary pin" means a metal rod driven into the marrow space of a bone."

The foregoing construction comports with the usage of the term "intramedullary pin" in various references including issued patents. By way of example, a search of the term "intramedullary pin" in the U.S. PTO database of issued patents results in the retrieval of 30 patents. (See, e.g., Attachment A which is a printout of the results of such a search which is provided for the convenience of the Board). A random check of these patents shows that the term "intramedullary pin" is uniformly used to describe a metal

rod driven into the marrow space of a bone. (See, e.g., U.S. Patent Nos. 4,178,640 and 5,248,313).

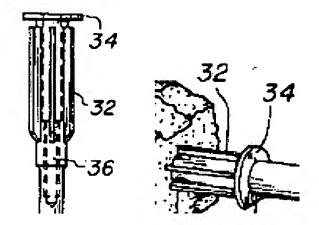
Finally, a search of the term "intramedullary pin" on the internet using Google <sup>TM</sup> results in about 10,800 hits. As evidenced by the descriptions of the matching hits, an "intramedullary pin" is uniformly used to describe a metal rod used to provide structural support to or to obtain structural support from, and in physical contact with, a bone. (A printout of the first page of the results of such a search is provided for the convenience of the Board as Attachment B). Therefore, a person of ordinary skill in the art reading the Appellants' claim in the context of the specification would construe "intramedullary pin" to be a metal rod driven into the marrow of a bone and in physical contact with at least a portion of the bone.

Accordingly, because the Examiner's construction of the term "intramedullary pin" so as to include the screw 182 does not comport with the meaning of an "intramedullary pin" as that term is understood by those of ordinary skill in the art, particularly when the term is construed in consideration of the Appellants' claim and in the context of the specification, the Examiner's construction of the term "intramedullary pin" so as to encompass the screw 182 of Ritter is unreasonable. Therefore, the rejection of the Appellants' claims based upon the Examiner's allegation that the screw 182 of Ritter is an intramedullary pin should be reversed.

#### 5. A Fin is Not a Slot

The belated identification of the alleged intramedullary pin of Ritter also supports the Appellants' contention that the flutes 32 of Ritter are not guide slots as alleged by the

Examiner. (See, e.g., Examiner's Answer at page 6). FIG. 20 of Ritter does not identify the flutes 32. FIGS. 2 and 5, portions of which are set forth below, do identify the flutes 32.



As clearly evidenced by FIGs. 2 and 5, the flutes 32 of Ritter are shown as planar objects which project outwardly from the outer surface of the intramedullary rod 30.

Thus, the flutes 32 "are used to prevent rotation of the intramedullary rod 30 when the intramedullary rod 30 is located in the femur 27." (Ritter at column 3, line 66 through column 4, lines 2). The screw 182, as discussed above, is positioned within the blind bore 36. Accordingly, when the device of Ritter is assembled with the screw 182 within the blind bore 36, the screw 182 does not interact with the flutes 32 in any fashion.

The Federal Circuit has stated that to reject a claim based upon anticipation, "[t]he elements must be arranged as required by the claim, but this is not an *ipsissimis* verbis test, i.e., identity of terminology is not required." *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Thus, while the nomenclature attached to the elements may vary, an element must be arranged in the prior art in the same manner recited in a claim to be anticipatory.

Claim 28 requires an intramedullary pin to be "received within said guide slot of said positioning member of said instrument." The word "received" is defined as "to hold, bear, or contain: The nut receives a bolt and a washer. The plaster receives the impression of the mold." *Dictionary.com Unabridged* (v 1.1), Based on the Random House Unabridged Dictionary, © Random House, Inc. (2006). Moreover, claim 28 recites that the guide slot is "configured to receive an intramedullary pin." The word "configured" is defined as "[t]o design, arrange, set up, or shape with a view to specific applications or uses." *The American Heritage® Dictionary of the English Language*, Fourth Edition, Houghton Mifflin Company (2000). Thus, the claim clearly recites limitations requiring a single component (the guide slot) to be designed, arranged, set up, or shaped to hold, bear, or contain another component (the intramedullary pin).

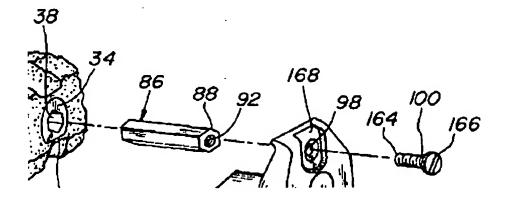
As set forth above, the screw 182 is not an intramedullary pin. Nonetheless, assuming *arguendo* that the screw 182 is an intramedullary pin, none of the flutes 32 are arranged in the manner required by the claim. Specifically, none of the flutes 32, alone or in combination, is designed, arranged, set up, or shaped to hold, bear, or contain the screw 182. The screw 182 only interacts with the blind bore 36 and the angled support member 180. (Ritter at column 11, lines 6-8 and FIG. 20). In fact, Ritter fails to disclose *any* component that is held, born, or contained within one of the flutes 32. Rather, each of the flutes 32 is planar in shape, and thus incapable of holding, bearing, or containing *anything* therein. Therefore, a planar flute 32 which is spaced apart from the screw 182 cannot reasonably be said to hold, bear, or contain the screw 182.

Because none of the flutes 32 of Ritter are a "guide slot" as recited in the claims, the rejection of the Appellants' claims based upon the Examiner's allegation that the flutes 32 are guide slots should be reversed.

#### 3. Ritter Contradicts the Examiner's Description of the Flange of Ritter

The Examiner further alleges that the flange 34 of Ritter is a "coupler" that couples with the "augment" 96 of Ritter citing to FIG. 8 of Ritter and definitions of a coupler as "something that joins or links two things together." (Examiner's Answer at page 5). The conclusion drawn by the Examiner cannot reasonably be drawn from the portions of Ritter relied upon by the Examiner. Moreover, the allegations of the Examiner are specifically contradicted by the actual disclosure of Ritter.

The same online dictionary used by the Examiner defines the verb "join" as "to put or bring together so as to form a unit" and the word "link" as "to couple or connect by or as if by a link." *Merriam Webster online Dictionary*, 2006-2007. Thus, to be a "coupler" some interaction between the flange 34 and the femoral provisional 96 of Ritter is necessary. A portion of FIG. 8 of Ritter, which the Examiner alleges proves that the flange 34 is a coupler, is set forth below.



As is evident from a consideration of FIG. 8, FIG. 8 is an exploded view of various components. The U.S. PTO Guide for the Preparation of Patent Drawings (1993) states that in patents, exploded views are used "to show the relationship or order of assembly of various parts." Thus, while FIG. 8 is useful for showing that the angled support member 88 is located between the femoral provisional 96 and the intramedullary rod 30, actual contact points between the components *cannot* be determined based solely upon FIG. 8. Therefore, FIG. 8 *does not* provide sufficient evidence to reasonably conclude that the flange 34 is a coupler.

Moreover, the Examiner's conclusion is contrary to the description of Ritter.

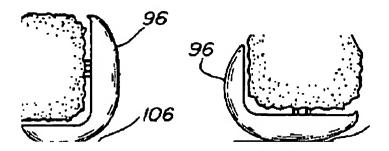
Ritter actually teaches that the "hex portion 38 is used for attaching other instrumentation to intramedullary rod 30." (Ritter at column 4, lines 9-10). Ritter also teaches that the "exterior of the angled support member 86 is hexed shaped so as to be operable to be inserted into the hex portion 38 of intramedullary rod 30." (Ritter at column 5, lines 20-24). Therefore, Ritter describes the angled support member 86 as interacting with the hex portion 38, not the flange 34.

Additionally, Ritter discloses that a "screw 58 within the blind bore 36 determines the depth of the blind bore 36" and "[i]n the method of the present invention, the screw 58 should be first positioned proximally as shown in FIG. 11 to allow for maximum adjustability." (Ritter at column 7, lines 53-60). Therefore, the method disclosed by Ritter sets the depth of the bore 36 at the deepest possible depth.

In accordance with the method, the angled support member 86 is attached to the femoral provisional 96 and then placed within the hex portion 38. (Ritter at column 8, lines 26-43). Thus, the angled support member 86, in the method disclosed, is placed as

deeply within the blind bore 36 as possible since the screw 58 is in the position of FIG.

Finally, Ritter teaches that using the disclosed device in the above described manner results in the configuration shown in FIGs. 9 and 10 of Ritter. (Ritter at column 8, lines 44-48). Portions of FIGs. 9 and 10 of Ritter are set forth below.



Therefore, FIGs. 9 and 10 of Ritter clearly show that when the angled support 86 is inserted as far as possible into the blind bore 36 in accordance with the teaching of Ritter, there is *no contact whatsoever* between the femoral provisional 96 and the flange 34. Rather, the only contact disclosed by Ritter is between the angled support member 86 and the hex portion 38 of the intramedullary rod 30 and the screw 58 in the blind bore 36.

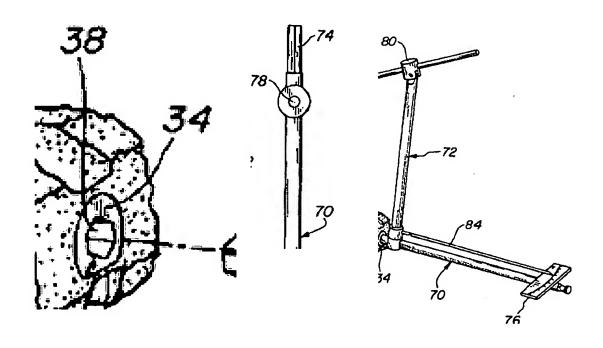
Therefore, because FIG. 8 of Ritter does not provide sufficient detail to support the conclusion drawn by the Examiner as to the function of the flange 34 as a coupler which couples with the femoral provisional 96, and because the conclusion drawn by the Examiner as to the function of the flange 34 as a coupler which couples with the femoral provisional 96 is directly contradicted by the actual disclosure of Ritter wherein the angled support member 86 is inserted into the hex portion 38, the flange 34 is not a "coupler" as recited in the Appellants' claims. Consequently, the rejection of the

Appellants' claims based upon the Examiner's allegation that the flange of Ritter is a coupler should be reversed.

#### 4. Ritter Contradicts the Examiner's Description of the Bore of Ritter

The Examiner has also alleged that Ritter discloses "a connector member, 38, having a first mating feature" and "a femoral resection guide, 70, having a second mating feature, 78, that mates with the first mating feature." (Examiner's Answer at pages 3 and 4). The Examiner's allegation is unreasonable.

Ritter discloses a "hex portion 38" which is part of the intramedullary rod 30 (Ritter at column 4, lines 5-6 and FIG. 8, a portion of which is set forth below) and an extension member 70 with "a bore 78 which is used for attaching the direction member 72 to the extension member 70" (Ritter at column 5, lines 7-9 and FIGs. 2 and 7, portions of which are set forth below).



The Examiner thus alleges that a "hole" mates with a "bore." The word "mate" may be defined as "to join, fit, or associate suitably." Dictionary.com Unabridged (v 1.1), Based on the Random House Unabridged Dictionary, © Random House, Inc. (2006). The Examiner has not explained the manner in which the hole and bore of Ritter join, fit, or associate suitably, and any such joining, fitting or association is not evident. Moreover, Ritter states that "[t]he extension member 70 comprises a hex portion 74 which is operable to engage the hex portion 38 of the intramedullary rod 30" and that bore 78 "is used for attaching the direction member 72 to the extension member 70" (Ritter at column 5, lines 1-9). Thus, the bore 78 is not used with the hex portion 38.

Therefore, because the allegation made by the Examiner as to the interaction between the hex portion 38 and the bore 78 is not supported by Ritter, the bore 78 is not a "mating feature" as recited in the Appellants' claims. Therefore, the rejection of the Appellants' claims based upon the Examiner's allegation that the bore 78 of Ritter is a mating feature should be reversed.

The Examiner Impermissibly Determines Proportions Based Upon a Drawing The Examiner's sole basis for alleging that the "pin 100" of Ritter enters within the bore of the "positioning member 30" is based upon a conclusion that "figure 8 clearly discloses that the pin, i.e. 100, is received in the second coupler, i.e. 86, wherein both the pin, i.e. 100 and the second coupler, i.e. 86, are received in the bore of the positioning member, i.e. 30. Thus, the pin, i.e. 100, is received in the bore of the positioning member, i.e. 30." (Examiner's Answer at page 5). FIG. 8 cannot provide the requisite support for the Examiner's conclusion.

5.

As an initial matter, the Examiner's conclusion is logically flawed. Merely because the screw 100 is threaded into the angled support member 86 and the angled support member 86 is inserted within the hex portion 38 of the intramedullary rod 30 does prove whether or not the screw 100 is ever located "within said bore" as recited in the claims *unless* the screw 100 is inserted within the angled support member 86 *and* extends completely along the length of the angled support member 86. The Examiner has failed to identify any teaching, disclosure or suggestion in Ritter that the screw 100 extends completely along the length of the angled support member 86. Therefore, the Examiner's argument is logically flawed.

Moreover, the Examiner's sole basis for the determination that the screw 100 is received within the bore of the intramedullary rod is an interpretation of FIG. 8. Even if FIG. 8 appeared to show that the screw 100 was as long or longer than the angled support 86, such a depiction of relative proportions in an exploded view is not sufficient to prove that the screw 100 extends into the intramedullary rod 30. The Federal Circuit has stated that "patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." *Hockerson-Halberstadt*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000). The Examiner has failed to identify any such statement in Ritter. Therefore, reliance upon any relative proportions set forth in FIG. 8 is misplaced.

Finally, Ritter does not inherently disclose such a relationship since the screw 100 is merely used to attach the femoral prosthetic 96 to the angled support member 86.

(Ritter at column 6, lines 7-12). Therefore, because placing the screw 100 within the hex portion 38 is not necessary to the function identified by Ritter for the screw 100, Ritter

10/748,449

does not inherently disclose that the screw 100 is received in the bore of the

intramedullary rod 30.

Accordingly, the rejection of the Appellants' claims based upon the Examiner's

allegation that the screw 100 of Ritter is received in the bore of the intramedullary rod 30

should be reversed.

Conclusion

For the reasons set forth above and for all of the reasons set forth in the

Appellants' Appeal Brief, claims 24, 27, 28, 31 and 32 are not anticipated by Ritter and

claims 25, 26, 29 and 30 are not obvious over Ritter in view of Fraser. Accordingly, the

Board of Appeals is respectfully requested to reverse the rejections of claims 24-32.

Respectfully submitted,

MAGINOT, MOORE & BECK

/James D. Wood/

James D. Wood

Attorney for Appellant Registration No. 43,285

Maginot, Moore & Beck Chase Tower

January 17, 2007

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14

# ATTACHMENT A

## USPTO PATENT FULL-TEXT AND IMAGE DATABASE

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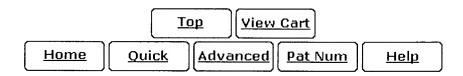
PAT.

NO.

Title

- 1 7,135,042 T Surgical implant
- 2 7,063,706 T Distraction device
- 3 6,855,146 **T** Intramedullary nail
- 4 6,554,833 **T** Expandable orthopedic device
- 5 6,551,321 **T** Flexible intramedullary nail
- 6 6,533,788 T Locking device for intramedullary pin fixation
- 7 6,510,334 T Method of producing an endoprosthesis as a joint substitute for a knee joint
- 8 6,447,513 **T** Fixation device
- 9 6,261,289 T Expandable orthopedic device
- 10 6,034,295 T Implantable device having an internal electrode for stimulating growth of tissue
- 11 5,976,138 **T** Distraction system for long bones
- 12 5,735,277 **T** Method of producing an endoprosthesis as a joint substitute for knee-joints
- 13 5,425,770 T Calcium phosphate/atelopeptide collagen compositions for bone repair
- 14 5,407,420 **T** Fully adjustable shoulder brace
- 15 RE34,871 **T** Process of endosteal fixation of a ligament
- 16 5,295,991 **T** Surgical instrument for positioning osteosynthetic elements
- 17 5,281,225 T Intramedullary pin with self-locking end for metadiaphyseal fractures of long bones
- 18 5,281,224 T Centering means for holes of intramedullary nails
- 19 5,248,313 T Fibular intramedullary rod
- 20 5,246,457 T Xenogeneic collagen/mineral preparations in bone repair
- 21 4,728,330 T Prosthetic bone or tooth implant and a method of surgically implanting the same
- 22 4,682,590 **T** Method of inserting intramedullary coupled pin
- 23 4,443,941 T Intramedullary pin cutting instrument

- 24 4,379,451 T Intramedullary hip pin and cortical plate
- 25 4,278,668 **T** Pure 17 alpha-ethynyl(5 alpha), androst-2-ene,17 beta-cl, process for its preparation and therapeutical applications of the same
- 26 4,229,841 **T** Wrist prosthesis
- 27 4,190,044 T Telescoping intermedullary pin
- 28 <u>4,178,640</u> **T** Wrist prosthesis
- 29 4,146,022 T Fracture fixation by cerclage utilizing cortical bone tack and pull-out tension device
- 30 <u>3,990,438</u> **T** Bone fracture fixation and compression apparatus



"Intramedullary pin" - Google Search

Page 1 of 2

ATTACHMENT B

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1671-0281 Reply Brief.doc - which anticipates the intramedullary pin re United States Patent: 399.. - to anchor an intramedullary pin within the

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Intramedullary pin fixation in clavicular fractures: A study comparing the use of small and large pins from Journal of Orthopaedic Surgery in Health ...
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The S-shaped clavicle poses a problem for intramedullary pin fixation. Stability of fracture fixation is closely related to the length of intramedullary pin ... www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve& db=PubMed&list\_uids=12468854&dopt=Abstract - Similar pages

Modified **intramedullary pin** technique for repair of distal femoral ... A modified **intramedullary pin** technique for surgical repair of distal femoral physeal fractures in d...

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external fixation, an **intramedullary pin**, and a bone plate. An external fixation consists of a rigid metal or acrylic frame outside the broken limb. ... www.cvm.uiuc.edu/petcolumns/showarticle.cfm?id=125 - 9k - Cached - Similar pages

In vitro mechanical evaluation on the use of an intramedullary pin ... By improving construct stability, addition of an intramedullary pin to the traditional BPA technique may lessen implant-related complications and improve ... cat.inist.fr/?aModele=afficheN&cpsidt=16382548 - Similar pages

Wrist arthrodesis: a combined intramedullary pin and autogenous ... Wrist arthrodesis: a combined intramedullary pin and autogenous iliac crest bone graft technique. DH LEE, RE CARROLL The Journal of hand surgery(St. Louis, ... cat.inist.fr/?aModele=afficheN&cpsidt=3558131 - Similar pages

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File Format: PDF/Adobe Acrobat Intramedullary Pin-Plate with a Dynamic Compression Plate for ... To compare the biomechanical properties of a prototype intramedullary pin-plate ... www.blackwell-synergy.com/doi/pdf/10.1046/j.1532-950x.2004.04010.x - Similar pages

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Nonunion of the Fractured Clavicle

Another form of surgical treatment is **intramedullary pin** fixation and autogenous bone ... In addition, the **intramedullary pin** is a load-sharing device, ... japan.medscape.com/viewarticle/410427\_4 - 31k - Cached - Similar pages

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